Homeopathic Drug Review Presentation by Terry Cotter,
Terra-Medica Inc

Introduction

I am a Bachelor of Science graduate in Biology. My education has included Parasitology, Microbiology, Histology and Toxicology. For a short time I worked in a toxicology laboratory evaluating environmental pesticide residues. Later I became interested in entrepreneurial activities and then business management in a large corporation.

My background includes experiences in trade association boards, chamber of commerce executives, as an elected official and as an appointed representative to inter-government committees.

Today I am responding as a representative of the product distributor Terra-Medica Inc.. Our operations center is based in Ferndale WA. We are an importer, distributor and practitioner educator to professional markets on behalf of homeopathic remedy manufacturers in Germany and Switzerland.

I am not a practitioner but I have spent a large part of the past 6 years in conferences and education programs connected to the CAM (Complementary and Alternative Medicine) and naturopathic medical modalities and its professional members.

The Review Process

The Homeopathy Review hearing dates were announced on March 27, 2015. I discovered the announcement via a peer link on social media. I do not know how the notice of the hearings was conveyed to the many medical boards, medical schools and professional/industrial associations who are aligned to homeopathy, CAM and natural medicine approaches. I hope it was but it seems to me many medical community members have not been aware of this announcement.

While I am typing my own submission to meet the 5pm deadline April 13, 2015, I am continuing to respond to calls from medical practitioners who do not understand what is happening. Many doctors seem to be getting home from spring vacations last week and this week.

It is my opinion that the HPUS Board, an important FDA Advisory Mechanism in recent decades, is comprised of the very professionals who should be helping gather valuable and broad input. They will know virtually all of the associations, initiatives and research projects building upon successes locally and internationally.

My own opinion is that there is no evidence provided to me by practitioners utilizing these medical applications that has ever suggested a need for a broad review or changes to the Compliance Policy Guide. I am convinced that **Freedom to Choose**, for doctors, patients and the public is the predominant subject at risk.

The story about 'using a sledgehammer to swat a fly' comes to mind again and again as I consider this review announcement. The rushed process seems entirely out of step with urgency of the reality and I detect that this causes great concern for many doctors. I have found that these professionals, who are on the community's side when it comes to medical safety and health innovations, always make themselves available for consultation.

Safety, Risk and Efficacy

I meet healthcare practitioners at events across North America and in Europe. These licensed professionals have 8 to 10 years of post-graduate training in a variety of medical fields including MD, ND, DC, HD, DDS, LAc, TCM. These experts should be the go-to people for discussions about safety and efficacy issues. They are on the front lines of those daily experiences.

I have attended conferences hosted by Washington Association of Naturopathic Physicians, Oregon Association of Naturopathic Physicians, Arizona Naturopathic Medical Association, SPARC, Marion Institute Biological Medicine Network, American College for Advancement in Medicine, A4M, Parker Chiropractic Seminars and several others. I have also attended conference events in Canada,

Germany and Dubai. These organizations represent many thousands of practitioners and tens of thousands of patient experiences in recent decades.

In my experience doctors build their medicament toolbox with treatment options they regard to be reliable and safe. In daily healthcare consequences, it is the patient who ignorantly suffers from the loss when the doctor is forced to choose a less optimal option remaining in the toolbox.

Print, broadcast and web media seem to regularly confuse homeopathy with herbal medicines, other OTC drugs, syrups, tonics, foods and supplements. It also seems very unlikely that a comment from a confused consumer working from memory would ever be further investigated for validity.

Considering the product confusion in media already, and further perpetuated by stories I will tell today, I think about Jay Leno's 'Jay Walk' segments where most people on the sidewalk couldn't identify which country is on the southern border of Nevada.

I have asked myself how likely is it that a small-sample consumer goods poll will accurately measure the market size of a specialty medical modality like this. I prefer to use actual pharmaceutical trade statistics, not an extrapolation of a consumer good survey to estimate $3 B ! That figure seems far out of step with the reality I see on the ground. I expect the estimate may be amiss by 300 - 400% but that is my intuitive opinion.

Dialogue: The Practitioners, Public and The Media

There is a fundamental advocacy weakness in the CAM and natural medicine communities in contrast to other industries. On the one hand the doctors are sought out through word of mouth, and on the other hand doctors are ill-equipped to tell success stories effectively to the broader community.

Practitioners are too busy helping patients to speak up. When they leave to attend a hearing the practice, the entire business, employees and services must close. Advocating for themselves is prohibitively costly.

A recent example of damage from weak consultation is the 2015 NY case. The regulator used the wrong tests to open gotcha campaign to curb 'risks' from dealers of herbal supplements. The industry consultations prior to the announcements weren't presented. Of course, we must doubt it ever happened or they would've used proper testing.

Media rushed to print flashy art, headlines and inflict reputation damage on the private sector for well over 48 hours. Later the regulator agreed they used an invalid test method. The responsible media didn't even notice. Many digital articles still carry the original headline. Worse, the regulator seems to continue to insist new rules are needed. Is this style of oversight and the consequences something the public should expect in a regulator?

This is a lesson about the damage to community health issues and private citizens that a regulator can precipitate unintentionally or intentionally. I think it also erodes public trust and that may be even more important. Consultation on complicated matters needs to engage the right people.

Consequently, from what I see so far, I am expecting the review will become a public campaign for hearts and minds. Attention-winning headlines will appear soon. If I were to choose a headline it is simply that the public and their doctors should sustain a **right to choose**.

Remedies that do not provide effective benefits to the users eventually lose to better choices anyway. In the case of access to homeopathy 100 years of safe patient benefits and continuing international innovation should tell it's own story.

Another example that speaks to the responsibility of balancing risk, benefits, consultation and media is the case of Terra-Medica's Pleo Sanum homeopathic product distribution. In this example I cannot speak directly for the manufacturer but I can relate the story from the documents we have seen and our own very public experience.

In March 2013 the FDA sent a 2 person GMP audit team to the German pharmaceutical manufacturing facilities and they spent 7 intensive days on the sites.

As a frame of reference in measuring the balance of 'effort and resources spent vs measurable risk', this German manufacturer had been exporting +/- $1.5 M of product to us here annually.

The cost to conduct the remote audit of a facility that is already GMP regulated by the German Trade Supervisory Board equals roughly 10% of the annual value of the entire importation. It's an important consideration in understanding relative policy guidance that uses public resources like remote inspections and reviews in mitigation of scalable public safety risks.

The German manufacturer prepared an internal calendar action plan for progressive implementation of responsive housekeeping actions requested during the audit and provided it to the FDA. I don't find any information that the FDA notified the German Trade Supervisory Board before the audit or with post-audit results. Perhaps it should be standard protocol as a courtesy to local public health.

Anyone who works within regulatory oversight operating a Food or Drug manufacturing facility is very familiar with receiving adjustment orders resultant from inspections.

Five months of action plan progress was near conclusion when FDA issued an import alert, which froze an active shipment in transit. There was no advance notice of the alert action provided to the manufacturer or to Terra-Medica. The shipment was returned at great expense after a long storage while we sought information.

In April of 2014 the manufacturer received a new FDA report of a theoretical risk of possible product cross contamination. The German Trade Supervisory Board regularly monitors GMP aspects of the very proprietary processes that were being noted. Neither the local GMP oversight authorities or the manufacturer were consulted for details relating to the process designs that prevent the asserted 'theoretical' problem.

Despite a record of zero contaminations in over 40 years of production history and an available science dossier outlining the product safety that was declined,

Terra-Medica was *encouraged* to conduct a 'voluntary recall' in the USA in 2014. Media accepted the FDA press release without investigation and began printing flippant headlines and satire about contaminated products.

FDA sent their press release to global health authorities and this additionally provoked severe international confusion over a matter the German GMP authority had already reviewed. This international confusion caused the German regulator to conduct a new site inspection.

The new inspection results heightened local confidence that the Pleo Sanum manufacturer has been producing safe products. We were all relieved.

Since late 2014 the FDA has been in possession of those inspection conclusions from the German Government Trade Supervisory Board. The German authority and those in the international community waits for any response to the 'all clear' findings. The medical community here has been in shock for 2 years and I receive update calls almost daily from both doctors and patients desperate to resume activity.

Again, the reason for the story is to underscore the importance of consultation with all the available expert resources. Poor outcomes have serious detrimental results. Interrupted medicament access for the professionals and the public has been devastating for them and for us.

I have one other example pertaining to open consultation and dialogue in regulatory processes. Rubimed homeopathic remedies are produced by a Swiss GMP manufacturer and have been available globally since 1993 and in North America since 2002. There is a dedicated Zurich-based professional society of 1,200 members to support this modality.

In 2008 FDA required Terra-Medica to refer to the USDA because an ingredient in selected 3.5oz shelf-ready packages is a diluted sterile extract of animal origin. I reviewed the guidance rules and it seemed to me that our products were exempt from USDA oversight because they are all final dose forms. The analyst did not agree and would not consult with other experts.

USDA stated we required an annual permit to certify each shipment is biohazard-free. We did this annually and paid our fees on time. Later, in 2012 a USDA staff person declined to re-issue the permit because a staff member moved and the name and address changed on the forms. In late 2014, after 10 months of debate and stock-outs, we obtained a renewed permit.

The first 2014 importation was stopped again and I contacted a senior USDA staffer to have a 'shipper name' added to satisfy another official. In that conversation she asked "Is all the product in finished packages?". I said yes. She said "Your products are actually exempt from our oversight anyway". She charged me $75 to amend the paper and the delivery was completed.

I asked this senior official for a short letter to assist less-knowledgeable staff next time. She told me it's not USDA policy to provide interpretive assistance to other staff through letters. We must 'take our chances' with the system at each importation.

In both stories we have watched while regulators have seemed to operate in isolation in determining policy. It is a culture that is frustrating to watch as it unfolds.

Today's message is not about our particular services, it is about this review and the working culture we hope it unfolds within.

I came to the hearing to present these illuminating stories because I want to provoke <u>mindful consideration</u> of the harm that can be caused by incomplete consultation.

I want to be considerate of the public trust but also remain a strong advocate for the public **Freedom to Choose.** Many of us in this profession believe *that* is the significant issue at risk. We must trust you to take proactive steps to assure all the appropriate expertise is heard.

<u>Regulatory Recommendations</u>

Not long ago homeopathic hospitals and education were widespread in America. In the last century the fiscal boom in orthodox medicine saw new profit centers evolve and facilities changed hands. The value of holistic approaches didn't leave the table, just the spotlight.

It seems to me that in recent years a renewed effort has been widespread to develop education programming, research and data collection pertaining to efficacy of CAM and naturopathic approach in healthcare generally.

In the CAM and naturopathic approach, homeopathic drug applications are not an island of treatment. These evolving tools are an important part in the broad palette of options utilized as they are appropriate in the individualized medicine approach.

Publications and reviews regarding the healthcare opportunities presented by homeopathy specifically, including evidence supporting a wide variety of applications and co-applications is abundant. These many publications record the professional experience and evidence and it is openly available in libraries, journals and the literature marketplace. These documents collectively speak to a significant categorical record of safety, economy and efficacy in helping the public at home and abroad.

Homeopathy isn't miracle medicine. Like any medicament category it has appropriate uses and there will be many circumstances where other methods will be recommended. The point to be made today is that homeopathic product access remains important in healthcare choice.

I recommend that FDA enter into **Mutual Recognition Agreements** with the European and other industrialized nations, just as most other progressive countries have done, specifically regarding GMP and registration standards. This will prevent the many issues we have observed and presented here: international confusion, unnecessary administrative costs, staff redundancy, and improve the opportunity for innovation to grow and local employment to follow in those steps.

I believe there is a need for regulators to be cognizant of a responsibility to provide stewardship to industry. Enable flexible function of the local economy

within the informed parameters of safety, choice, community benefits and opportunity for innovation.

What I can say by own experience in all accounts is that homeopathy is a very important, safe and effective treatment option.

I advise a determination to preserve the Compliance Policy Guide in the current state, and where possible, enhance access to similarly safe health technology innovations for the benefit of all our communities.

Thank you for your attention

Terry Cotter
1-888-415-0535